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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 811.842	03 19 2001	Charles J. Link	P04465US1	9222

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 06 30 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,842

Applicant(s)

LINK ET AL

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-50 and 53-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 53 is/are allowed.
- 6) ☒ Claim(s) 45-50, 54 and 57 is/are rejected.
- 7) ☐ Claim(s) 55, 56 and 58-74 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other _____

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DETAILED ACTION

Receipt is acknowledged of a reply, filed April 17, 2003 as Paper No. 16, to the previous Office Action. Amendments were made to the claims. Specifically, claims 1-44, 51 and 52 were cancelled and claims 53-74 were added. It is noted that in applicant's arguments, they are under the impression that claims 45-50 have also been cancelled. However, there are no such instructions in the response, therefore the claims are still pending in this application.

Claims 45-50 and 53-74 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, Paper No. 11, mailed October 19, 2002, that is not addressed in this action has been withdrawn.

With the exception of claims 45-50, applicant has cancelled all of the previously pending claims by amendment. As such, all arguments presented by applicant regarding the previous rejections are moot and will not be addressed further.

Because this Office Action either maintains rejections set forth in the previous Office Action or introduces new rejections that are necessitated by amendment, this Office Action is made FINAL.

Claim Objections

Claim 55 and 56 are objected to because of the following informalities: the claim recites two acronyms, SAVI and RACE; when reciting an acronym in a claim for the first time, it is proper to spell-out the meaning of the acronym. Appropriate correction is required.

Claims 58-74 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim 58 is multiply dependent on claim 60 which depends from itself

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because it is also dependent on claim 58. See MPEP § 608.01(n). Accordingly, the claims 58-74 have not been further treated on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 45-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons set forth in the previous Office Action.**

Claims 54 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. **This is a new rejection necessitated by amendments to the claims.**

Specifically, the claims recite a limitation wherein cells are sorted "into monoclonal or polyclonal subgroups based on their different levels of expression of said marker peptide." However, there is no description of what these monoclonal or polyclonal subgroups comprise or

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how they are defined, therefore the skilled artisan would not be able to envision how to separate cells into such monoclonal and polyclonal subgroups. Therefore, the instant specification does not satisfy the written description requirement for the claimed subject matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54 and 57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54 and 57 contain the limitations "monoclonal" and "polyclonal" as it refers to subgroups of cells. These terms are not defined anywhere in the specification, therefore the metes and bounds of what determines a monoclonal or polyclonal subgroup of cells is unclear.

Response to Arguments Regarding Claim Rejections - 35 USC § 112

Applicant has argued that the rejection of claims 45-50 has been traversed by cancellation of claims 45-50. However, in the amendment filed April 17, 2003, only claims 1-44, 51 and 52 have been cancelled. Therefore, claims 45-50 are still pending, and remain rejected as set forth in the previous Office Action.

Allowable Subject Matter

Claim 53 is allowed.

Claims 55 and 56 are objected to as containing informalities.

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Claims 45-50, 54 and 57 are rejected.

Claims 58-74 have not been considered on the merits because they are objected to for being in improper multiple-dependent format.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
June 25, 2003

DAVID A. LAMBERTSON
DIRECTOR
David A. Lambertson